APR -1 2009

K083310

510 (k) Summary of Safety and Effectiveness for Spine & Trauma iCT

Manufacturer:

Address: BrainLAB AG
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85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Per Persson

Summary Date: March 09, 2008

Device Name:

Trade name: Spine & Trauma iCT

Common/Classification Name: BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
VV Fluoro 3D (K 070106)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

BrainLAB **Spine & Trauma iCT** is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 3D image data.

Spine & Trauma iCT enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system.

The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired CT image.

Device Description:
Spine & Trauma iCT is a device that allows surgical planning and navigation. It links a surgical instrument, (tracked by passive marker sensor system) to a location on a virtual computer image, which is based on patient's preoperative or intraoperative 3D information of a CT dataset
The device enables the navigation based on 3D data.
Based on 3D data, the procedure of linking the surgical instrument to the virtual computer image is achieved by performing registration methods as paired point matching, region matching or by an automatic registration.
The automatic registration is based on an initial CT- scanner calibration and on the spatial position of CT- scanner and patient at the beginning of the scan. The calibrated volume is scanned and the 3D dataset and registration information is sent to the navigation computer. Thus, automatic registration is available right after patient scanning during surgery.
After registration, the device assists the surgeon in performing certain surgical procedures as described in the indications for use.

Substantial equivalence:
Spine & Trauma iCT Module has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device VV Fluoro 3D (K070106).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BrainLAB AG
% Mr. Per Persson
Kapellenstrasse 12
85622 Feldkirchen
Germany

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Re: K083310
Trade/Device Name: Spine & Trauma iCT
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: March 17, 2009
Received: March 19, 2009

Dear Mr. Persson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083310

Device Name: Spine & Trauma iCT

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Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kwon for MKH 3/31/09

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083310